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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,831	01/24/2001	David Houze	NOPH/100/JGK	7241

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/768,831	Houze et al.
Examiner	**Art Unit**
Isis Ghali	1615

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 25, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-30 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-30 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' specification, drawing, and petition for extension of time, all files 11/5/2001; and IDS, filed 3/12/2002.

Claim Objections

1. Claim 11 objected to because of the following informalities: typographical error "two polymer polymers". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-12, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al., US 4,390,520 ('520).

US '520 disclosed a dermal adhesive composition comprising a medication and copolymer which has pressure sensitive adhesive properties. The copolymer is a blend of more than one acrylic base polymer having a functional group. Suitable functional

groups include carboxyl and hydroxyl groups which inherently having different functionality and different solubility parameters. Preferred functional monomers having carboxyl group are acrylic acid and vinyl acetate. The reference disclosed hydroxy ethyl acrylate as a monomer having hydroxyl functional group. Vinyl acetate is preferred from the standpoint of view of active ingredient releasing property (greater flux), safety with respect to skin stimulation and improvement of adhesive properties to the skin. The monomers having functional groups are incorporated in the copolymer in an amount of about 0.1 to 20 % by weight. The vinyl monomers are incorporated into the copolymer in an amount of about 1 to 50 % by weight. See the abstract; col.3, lines 13-18, 30-65. The limitation of the above claims are met by '520.

4. Claims 1-4, 6-8, 11, 12, 19, 20, 26- 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Xia et al., US 5,693,335 ('335).

US '335 disclosed a dermal composition comprising a drug and matrix of one or more monomer having one or more functional groups which provide sites for cross linking. Monomers disclosed by the reference are acrylic based polymers such as vinyl acetate, acrylic acid and hydroxy ethyl acrylate which inherently having different functionality and different solubility parameters. The reference disclosed a method of making the dermal delivery device that includes the steps of mixing the adhesives and the drug, casting the matrix onto the backing, removing the solvent from the mixture by

drying and applying the release liner. The amount of vinyl acetate in the matrix is 28 % and hydroxy ethyl acrylate is 67 % by weight. See col.2, lines 34-51; col.3, lines 51-58; example 1. The limitation of the above claims are met by '335.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '520, US '335, or Miranda et al., US 5,474,783 ('783) by itself or in view of any of US '520 or US '335.

US '783 is teaching a transdermal drug delivery system wherein the a blend of at least two polymers having two different solubility parameters adjusts the solubility of a drug in the polymeric blend and thereby modulate the delivery of the drug from the system and through the dermis. The reference is disclosing a pressure sensitive adhesive composition which is suitable as a matrix for controlled release of a bioactive agent therefrom comprising a blend of a first polymeric adhesive material having a first solubility parameter and a second polymeric adhesive material having a second solubility parameter, the first and second solubility parameters being different from one another. The blend therefore has a characteristic net solubility parameter which can be preselected to adjust the saturation concentration of the bioactive agent in the composition and thereby control its release either upward or downward depending upon whether the rate of release is to be enhanced or retarded. The transdermal permeation rate is also controlled by varying the relative proportions of the polymers comprising the multiple polymer adhesive system. The blend comprising an acrylic based polymer in an amount of 2-96 % and silicon based polymer in an amount 98-4 %. Drugs used in the composition include haloperidol, nicotine, clonidine and scopolamine. Functional monomers used by the reference are acrylic acid, DURO-TAK and hydroxy ethyl acetate. Method of preparation of the transdermal delivery device include the steps of mixing the ingredients, coating the formulation onto protective release liner drying solvents in the oven and applying a backing material. See the abstract; col.3, lines 36-

60; col.4, lines 15-16, 34-45, 40-44; col.6, lines 13-19; col.8, lines 3-5; col.9, lines 22-26, 51-54; col.10, line 54; col.11, lines 4, 8, 38; col.15, lines 3-6, 20-35, 50-55.

The reference differs from the instant claims because it does not teach the blend comprising two acrylic based polymer.

US '520 and '335 teach the blend of two acrylic based polymers as discussed under 102 rejections above but do not teach the particular drugs disclosed by the applicants.

It is within the skill in the art to select the one of the drugs known to be effective transdermally to be incorporated into the transdermal device according to a particular need. It is also within the skill in the art to select optimal parameters such as ratios and weight percents in order to achieve a beneficial effect.

It would have been obvious for one having ordinary skill in the art at the time the invention was made to replace the silicon based polymer of '783 with a second acrylic based polymer motivated by the teaching of '520 and '335 of using two different acrylic based polymers in the pressure sensitive adhesive matrix which have pressure sensitive adhesive properties at room temperature, and a dermal composition for administration of drugs would have been delivered with reasonable expectation of success to modulate the drug solubility and delivery rate in the composition.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,725,876 disclosed a transdermal composition comprising nicotine and a blend of one or more acrylic based adhesive.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600